



## ENZYMATIC THERAPY INCORPORATED

*What **Better** feels like.™*

April 26, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards™ Daily Multiple	Body Rewards™ Daily Multiple is the ideal multivitamin to use when following a low carbohydrate diet.*	Vitamin E (as d-alpha tocopheryl acid succinate), Vitamin A (50% beta carotene), Vitamin B12 (as cyanocobalamin), D-Biotin 1% on DCP Dihydrate, Vitamin A Acetate 500, Manganese (as manganese citrate), Selenium (as L-selenomethionine), Calcium (as tricalcium phosphate), Phosphorus (as tricalcium phosphate), Zinc (as Zinc Ascorbate), Chromium (as chromium picolinate), Boron (as sodium borate), Molybdenum (as sodium molybdate), Green Tea Extract, Magnesium Oxide, Vitamin C (ascorbic acid), Vitamin K1 (as phytonadione), Vitamin D (as cholecalciferol), Magnesium aspartate, Vanadium (as vanadyl sulfate), Pantothenic Acid (as calcium D-pantothenate), Thiamin (as

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		thiamin HCl) (Vitamin B1), Vitamin B6 (as pyridoxine HCl), Nicotinamide USP, Iodine (as potassium iodide 1% KI), Niacin, Folic Acid, Riboflavin (Vitamin B2)
--	--	--

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 


Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/26/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

  
Michael P. Devereux  
Chief Financial Officer



## ENZYMATIC THERAPY INCORPORATED

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**INTEGRATIVE THERAPEUTICS INC.™**  
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Tyler Encapsulations ♦ Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 ♦ F: 503.582.0467

**ENZYMATIC THERAPY®  
&  
PHYTOPHARMICA®**

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 ♦ F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 ♦ F: 920.469.4418 (Phyto)

April 27, 2004

Office of Nutritional Products, Labeling &  
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5100 Paint Branch Parkway  
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RE: Label Claims/Disclaimers


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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards™ Daily Multiple	As part of Body Rewards™ System, Daily Multiple supports healthy energy levels and the retention of healthy blood sugar levels that are already within normal limits.*	Vitamin E (as d-alpha tocopheryl acid succinate), Vitamin A (50% beta carotene), Vitamin B12 (as cyanocobalamin), D-Biotin 1% on DCP Dihydrate, Vitamin A Acetate 500, Manganese (as manganese citrate), Selenium (as L-selenomethionine), Calcium (as tricalcium phosphate), Phosphorus (as tricalcium phosphate), Zinc (as Zinc Ascorbate), Chromium (as chromium picolinate), Boron (as sodium borate), Molybdenum (as sodium molybdate), Green Tea Extract, Magnesium Oxide, Vitamin C (ascorbic acid), Vitamin K1 (as phytonadione), Vitamin D (as cholecalciferol), Magnesium aspartate, Vanadium (as vanadyl sulfate), Pantothenic Acid (as calcium D-pantothenate), Thiamin (as

		thiamin HCl) (Vitamin B1), Vitamin B6 (as pyridoxine HCl), Nicotinamide USP, Iodine (as potassium iodide 1% KI), Niacin, Folic Acid, Riboflavin (Vitamin B2)
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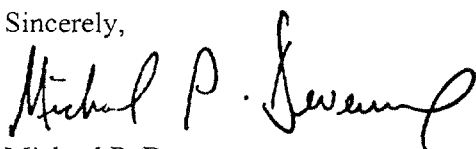
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/27/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards™ Daily Multiple	Supports the energy demands of a busy life*	Vitamin E (as d-alpha tocopheryl acid succinate), Vitamin A (50% beta carotene), Vitamin B12 (as cyanocobalamin), D-Biotin 1% on DCP Dihydrate, Vitamin A Acetate 500, Manganese (as manganese citrate), Selenium (as L-selenomethionine), Calcium (as tricalcium phosphate), Phosphorus (as tricalcium phosphate), Zinc (as Zinc Ascorbate), Chromium (as chromium picolinate), Boron (as sodium borate), Molybdenum (as sodium molybdate), Green Tea Extract, Magnesium Oxide, Vitamin C (ascorbic acid), Vitamin K1 (as phytonadione), Vitamin D (as cholecalciferol), Magnesium aspartate, Vanadium (as vanadyl sulfate), Pantothenic Acid (as calcium D-pantothenate), Thiamin (as

		thiamin HCl) (Vitamin B1), Vitamin B6 (as pyridoxine HCl), Nicotinamide USP, Iodine (as potassium iodide 1% KI), Niacin, Folic Acid, Riboflavin (Vitamin B2)
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*Robert Doster*

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Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/27/04

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April 28, 2004

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards™ Daily Multiple	Key nutrients in Daily Multiple include the herb green tea, the minerals vanadium and chromium, and vitamin B, C and E.* All have been clinically investigated for their effect on energy.*	Vitamin C (ascorbic acid), Vitamin E (as d-alpha tocopheryl acid succinate), Vitamin B12 (as cyanocobalamin), Thiamin (as thiamin HCl) (Vitamin B1), Vitamin B6 (as pyridoxine HCl), Riboflavin (Vitamin B2), Chromium (as chromium picolinate), Green Tea Extract, Vanadium (as vanadyl sulfate),

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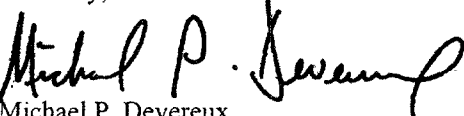
By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/30/04

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards™ Daily Multiple	Research has shown vitamin C is needed for growth, development, and for the use of energy by muscles and other body organs.*	Vitamin C (ascorbic acid)

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By: 

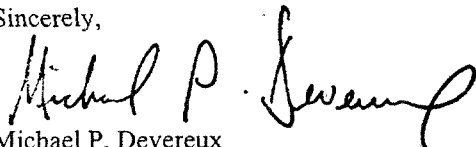
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/28/04

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards™ Daily Multiple	Vitamin E assists in the transportation of oxygen and supports healthy nerve transmissions, both crucial to energy and vitality.*	Vitamin E (as d-alpha tocopherol acid succinate)

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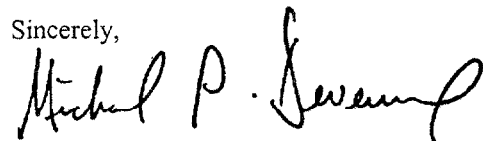
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards™ Daily Multiple	The B vitamins, a group of water-soluble vitamins, assist in the release of energy from foods.*	Vitamin B12 (as cyanocobalamin), Thiamin (as thiamin HCl) (Vitamin B1), Vitamin B6 (as pyridoxine HCl), Riboflavin (Vitamin B2)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster  
Robert Doster  
Title: Senior Vice President of Scientific Affairs

Date: 4/29/04

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards™ Daily Multiple	All of these vitamins are needed for the protection of body cells and tissues from free radical damage.*	Vitamin C (ascorbic acid), Vitamin E (as d-alpha tocopherol acid succinate), Vitamin B12 (as cyanocobalamin), Thiamin (as thiamin HCl) (Vitamin B1), Vitamin B6 (as pyridoxine HCl), Riboflavin (Vitamin B2)

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Title: Senior Vice President of Scientific Affairs

Date: 4/29/04

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards™ Daily Multiple	Chromium supports fat metabolism by insulin; helps turn protein into muscle; and supports healthy glucose conversion into energy.*	Chromium (as chromium picolinate)


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Robert Doster  
Title: Senior Vice President of Scientific Affairs

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards™ Daily Multiple	Vanadium supports healthy energy metabolism.*	Vanadium (as vandyl sulfate)

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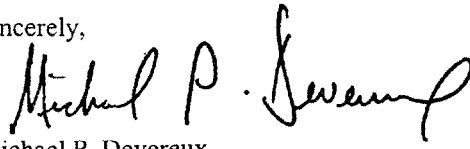
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards™ Daily Multiple	Green tea's health supportive properties have been repeatedly validated in clinical and laboratory research, including immune health and prevention of oxidative damage.*	Green Tea (Camellia sinensis) leaf extract 3:1

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College Park, MD 20740

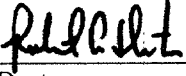
RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards™ Daily Multiple	Green tea naturally contains a small amount of caffeine. Caffeine has been shown in clinical trials to boost energy and stamina.*	Green Tea (Camellia sinensis) leaf extract 3:1

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

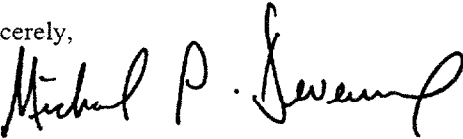
By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/30/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

  
Michael P. Devereux  
Chief Financial Officer



## ENZYMATIC THERAPY INCORPORATED

*What **Better** feels like.™*

### INTEGRATIVE THERAPEUTICS INC.™

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&  
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P: 920.469.1313 ♦ F: 888.570.6460 (Enzymatic)

P: 920.469.9099 ♦ F: 920.469.4418 (Phyto)

April 30, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards™ Daily Multiple	This formula contains important nutrients for energy and the support of blood sugar levels that are already within normal limits* - nutrients that may not be present at adequate intake levels when carbohydrate containing foods are not being regularly consumed.*	Vitamin A (50% beta carotene and as acetate), Vitamin C (ascorbic acid), Vitamin D (as cholecalciferol), Vitamin E, (as d-alpha tocopherol acid succinate), Vitamin K (as phytonadione), Thiamin (as thiamin HCl) (Vitamin B1), Riboflavin (Vitamin B2), Niacin (as niacin and niacinamide), Vitamin B6 (as pyridoxine HCl), Folic Acid, Vitamin B12 (as cyanocobalamin), Biotin, Panthothenic acid (as calcium D-pantothenate), Calcium (as tricalcium phosphate), Phosphorus (as tricalcium phosphate), Iodine (as potassium iodide 1% KI), Magnesium (as magnesium aspartate and magnesium oxide), Zinc (as zinc ascorbate), Selenium (as L-selenomethione), Manganese (as manganese citrate), Chromium (as chromium picolinate), Molybdenum (as sodium molybdate), Sodium, Green Tea (Camellia sinensis) leaf extract 3:1, Boron (as sodium borate), Vanadium (as vandy sulfate)



I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

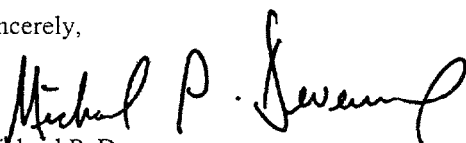
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